

Amendment and Response

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Serial No.: 10/749,602

Confirmation No.: 8548

Filed: 31 December 2003

For: IN OVO DELIVERY OF AN IMMUNOGEN CONTAINING IMPLANT

Remarks

The Office Action mailed 15 November 2006 has been received and reviewed. Claims 34, 67-69, 71, 72, and 84 having been amended, claims 45-66, 70, and 83 having been canceled, without prejudice, and claims 85-102 having been added, the pending claims are claims 34-44, 67-69, 71-82, and 84-102. Reconsideration and withdrawal of the rejections are respectfully requested.

The amendments to claims 34 and 69 are supported by the specification at, for instance, page 7, line 19 through page 8, line 11.

The amendments to claim 84 are supported by the specification at, for instance, page 6, lines 1-7, and page 7, line 19 through page 8, line 11.

New claim 87 is supported by originally filed claim 2. New claim 88 is supported by originally filed claim 3. New claim 89 is supported by originally filed claim 4. New claim 90 is supported by originally filed claim 5. New claims 91-93 are supported by the specification at, for instance, page 23, lines 7-10. New claim 94 is supported by the specification at, for instance, page 23, lines 7-10, and page 26, lines 3-10. New claim 95 is supported by originally filed claim 13. New claim 96 is supported by originally filed claim 6.

New claims 97-99 are supported by the specification at, for instance, page 20, line 22 through page 21, line 7.

New claims 100-102 are supported by the specification at, for instance, page 24, lines 15-19.

Status of Claims

Applicants note with appreciation the rejoinder of claims 71-82 for examination on the merits, and the Examiner's decision to characterize the Office Action as non-final.

Obviousness-Type Double Patenting Rejection

Claims 34-44 and 67-69 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,682,754. Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

The 35 U.S.C. §103 Rejections

The Examiner rejected claims 34, 37, 39-43, 67-69, 83, and 84 under 35 U.S.C. §103(a) as being unpatentable over Emery et al. (U.S. Patent No. 5,830,479) in view of Phelps et al. (U.S. Patent No. 5,339,766) in view of Genovese et al. (1998) in light of Sharma et al. (U.S. Patent No. 4,458,630). The Examiner rejected claims 34-44, 67-69, and 71-84 under 35 U.S.C. §103(a) as being unpatentable over Emery et al. (U.S. Patent No. 5,830,479) in view of Phelps et al. (U.S. Patent No. 5,339,766) and further in view of Evans et al. (U.S. Patent No. 6,500,438 B2) in view of Genovese et al. (1998) in light of Sharma et al. (U.S. Patent No. 4,458,630). These rejections are respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met (M.P.E.P. §2143). First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations.

In addition to the comments made in the previous response, the Examiner is requested to consider the following remarks. The independent claims have been amended as follows:

"A method for inducing immunity in a bird against a selected immunogen comprising: injecting a biocompatible implant into an egg, wherein the biocompatible implant comprises the selected immunogen . . . wherein the egg comprises maternal antibody to the selected immunogen, wherein the implant provides for sustained release of the

immunogen until the maternal antibodies are reduced so that the bird is capable of mounting an immune response to the immunogen" (independent claim 34);

"A method for inducing immunity in a bird against a selected immunogen comprising: injecting a biocompatible implant *in ovo*, wherein the biocompatible implant comprises the selected immunogen . . . and hatching eggs to result in birds, wherein the eggs comprise maternal antibody to the selected immunogen, wherein the implant provides for sustained release of the immunogen until a time when maternal antibodies of the birds to the immunogen are sufficiently reduced so that the birds are capable of mounting an immune response to the immunogen" (independent claim 69); and

"A method for inducing immunity in a population of birds against a selected immunogen comprising: injecting a biocompatible implant into a population of eggs that comprise maternal antibody to the selected immunogen . . . wherein the implant provides for sustained release of the immunogen until the maternal antibodies to the selected immunogen are reduced, and the birds hatched from the eggs are capable of mounting an immune response to the immunogen" (independent claim 84).

In evaluating the cited art the Examiner has made false assumptions and mis-characterizations. These false assumptions and mis-characterizations are detailed immediately below.

The Examiner notes that Example 3 of Emery et al. taught that immunization of birds at 3 weeks elicited an immune response (Office Action at page 8, lines 8-9). The Examiner assumes that the birds used in Example 3 of Emery et al. had maternal antibody. The Examiner is respectfully requested to consider the Rule 132 Declaration of Dr. Daryll A. Emery (copy included). In his Declaration, Dr. Emery states that the breeder hens were not vaccinated with the siderophore receptor protein vaccine, that the eggs laid by the breeder hens did not have any

antibody made in response to the siderophore receptor protein vaccine, and that the poult hatching from the eggs and used in Example 3 of Emery et al. did not have this type of maternal antibody (Declaration at paragraph 4). Moreover, Dr. Emery states that the skilled person would have known that the poult used in Example 3 of Emery et al. did not have maternal antibody to the vaccine being tested (Declaration at paragraph 5). Thus, the Examiner's assumption that the birds used in Example 3 of Emery et al. had maternal antibody to the immunizing antigen is false. Moreover, the skilled person would have recognized this.

The Examiner notes that according to Sharma, a bird's immune response is elicited even in the embryonic stage when vaccinated in-ovo (Office Action at page 9, first full paragraph). Dr. Emery states in his Declaration at paragraph 6 that the eggs used by Sharma did not include maternal antibody to the antigen administered in the vaccine. Thus, Sharma cannot be relied on by the Examiner as teaching that an immune response can be elicited by administering an immunogen to an egg that contains maternal antibody to the immunogen.

The Examiner asserts "that Genovese et al. clearly teaches that immunization within the first few days of hatching is beneficial because, to reiterate, Genovese et al. states ' . . . it would be advantageous to administer an agent which could potentiate an immediate immune response . . . ' " (emphasis added). The Examiner is requested to note that Genovese et al. does not immunize the chicks with an antigen that is intended to result in a protective active immune response. Instead, the day old chicks are treated with lymphokines derived from a virally transformed chicken T cell line (VILK), or a control of PBS or bovine serum albumin (see the Materials and Methods, the paragraph labeled Liver Invasion by Salmonella enteritidis). As explained by Genovese et al., the administration of lymphokines to poultry previous to or during the first week post-hatch potentiates the innate immunity of poultry (see second paragraph of Introduction). Moreover, Genovese et al. challenges the chicks 30 minutes after administration of the lymphokines. An immune response to an immunizing antigen cannot result in protection 30 minutes after the immunizing antigen is administered.

Genovese et al. may state that "[v]accinations used on newly hatched chicks and poult do provide some levels of protection from pathogens," but they also say "maternal antibodies may cause interference with the vaccine and the desired immune response to that vaccine" (see fifth paragraph of Results). Thus Genovese et al. notes that it is uncertain if a vaccine will function when it is administered to newly hatched chicks that have maternal antibody to the antigen.

The presence of maternal antibody in an animal has a significant effect on vaccination strategies. It is known that vaccinating an animal too early can result in an immune response that ranges from minimal to nonexistent. As evidence of this, the Examiner is requested to consider the Declaration of Dr. Daryll Emery. Dr. Emery states at paragraph 5 of his Declaration that "[i]t is well known that immunizing animals, including poult, with an antigen when maternal antibodies to the antigen are present is not desirable. The presence of maternal antibodies to the immunizing antigen can prevent the development of an active immune response to the antigen."

In view of the fact that both Emery et al. and Sharma do not use birds having maternal antibody to the administered immunogen, and the statement by Genovese et al. that maternal antibodies may cause interference with a vaccine and the desired immune response to that vaccine, the Examiner's statements regarding motivation are unfounded. For instance, while the Examiner states "the ordinary artisan would have been motivated to use the knowledge of Emery et al. to provide an implant . . . [o]ne of ordinary skill would have recognized that administration of the vaccine must have occurred at a time when the bird could illicit a response to the vaccine; or else the vaccination process would have been a failure" (Office Action at page 8). The skilled person would have recognized that Emery et al. used birds that did not have maternal antibody to the immunizing antigen, and would expect the vaccination process to be inhibited or prevented if maternal antibody were present.

Likewise, the Examiner's assertions regarding the reasonable expectations of the skilled person are not correct. Specifically, the assertion that "*in-ovo* inoculation *itself* would have

elicited an immune response in the embryo of the bird" (Office Action at page 10, lines 9-10, emphasis in original) is not correct because *in-ovo* inoculation would not necessarily elicit an immune response in an embryo if it contained "maternal antibody to the selected immunogen" (independent claims 34, 69, and 84). Likewise, the assertion "that sustained delivery of a siderophore receptor from a gram negative bacterium until 21 days post-hatch would have also elicited a positive immune response" (Office Action at page 10, lines 10-12) is not correct because administration of such an immunogen until 21 days post-hatch would not necessarily result in an immune response in birds containing maternal antibody to the immunogen, and since the birds referred to in independent claims 34, 69, and 84 hatch from eggs containing maternal antibody to the immunogen, the birds will also contain the maternal antibody.

The Examiner also states that "because an immune response would have been elicited, it is deemed that the maternal antibodies must have been sufficiently lowered" (Office Action at page 10, lines 17-19). It is unclear if the Examiner is referring to Emery et al. or Sharma; however, since both Emery et al. and Sharma used poults and eggs, respectively, that did not contain maternal antibody to the immunogen, this conclusion made by the Examiner is false.

With respect to the rejection of claims 34, 37, 39-43, 67-69, 83, and 84, Emery et al., Genovese et al., and Sharma et al. do not teach or suggest the present invention, and the deficiencies of these three references are not supplemented by Phelps et al. Likewise, with respect to the rejection of claims 34-44, 67-69, and 71-84, Emery et al., Genovese et al., and Sharma et al. do not teach or suggest the present invention, and the deficiencies of these three references are not supplemented by Phelps et al. or Evans et al.

With respect to the rejection of claims 34, 37, 39-43, 67-69, 83, and 84, independent claims 34, 69, and 84 recite "wherein the egg comprises maternal antibody to the selected immunogen," "wherein the eggs comprise maternal antibody to the selected immunogen," and "a population of eggs that comprise maternal antibody to the selected immunogen," respectively. The disclosures of Emery et al., Genovese et al., and Sharma et al. do not teach or suggest this. Evans et al. relates to *in ovo* vaccination against coccidiosis. Evans et al. do not teach or suggest

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"wherein the egg comprises maternal antibody to the selected immunogen," "wherein the eggs comprise maternal antibody to the selected immunogen," or "a population of eggs that comprise maternal antibody to the selected immunogen." Thus, Evans et al. does not supplement the deficiencies of Emery et al., Genovese et al., and Sharma et al. Since Evans et al. does not supplement the deficiencies of Emery et al., Genovese et al., and Sharma et al., the cited documents do not teach or suggest all the claim limitations. Thus, the Examiner has failed to establish a *prima facie* case of obviousness for claims 34, 37, 39-43, 67-69, 83, and 84.

Summary

It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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